

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Geena MALHORTA et al

Confirmation: 5437

Serial No.: 10/562,218

Group Art Unit: 3771

Filed: April 25, 2006

Examiner: DOUGLAS, STEVEN O.

For: **PHARMACEUTICAL DISPENSING AID**

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Reconsideration of the rejection of the claims in the Office Action of January 19, 2010, are respectfully requested in view of the following comments. Of even date herewith is filed a petition for extension of time together with the appropriate government fee therefore in order to make this Request for Reconsideration timely.

Reconsideration of the rejection of claims 1, 2, 11-12 and 14-17 under 35 U.S.C. 103 (a) as being unpatentable over Jordan (GB 2195544) is respectfully requested in view of the following comments.

The claimed invention as claimed in independent claim 1 for example, is directed to a metered dose inhaler comprising

a canister, a metering valve attached to the canister,

wherein the canister is sufficiently transparent that a formulation disposed within the canister is visible from the exterior of the canister and wherein the canister comprises polycarbonate and does not have any coating on the interior surface thereof.

While the Examiner characterizes the Jordan reference as disclosing a pharmaceutical inhaler that dispenses a metered dose comprising a canister made of a plastic material that is transparent and a metering valve, the Examiner concedes that Jordan "fails to disclose the plastic material as being at least partially or entirely polycarbonate".

While said Jordan reference does teach the use of plastic material for the manufacture of pharmaceutical inhaler/dispensers, the reference does not recognize a problem with plastics materials which, through experimentation and inventive activity, have been identified by the applicant and addressed by the present invention.

Specifically, the present invention ensures the interior walls of an inhaler do not suffer a build up of medicament, as previously mentioned in the Specification. However, in addition, the applicant has found that apparently suitable plastics materials are, in practice, not suitable in certain ambient conditions.

In particular, studies carried out by the applicant have revealed that medicament containers made from transparent plastics, such as Polyethylene Terephthalate (PET) tend to deform in time when stored at higher ambient temperatures. For example, when stored for 10 days in ambient temperatures of 40°C, experiments show that PET containers expand outwardly, blowing up like a balloon. A photograph of such a deformed container is attached as Exhibit 1. Such PET containers are unable to withstand the forces exerted by the pressurized fluid held within them when exposed to high room temperatures. Fifty PET containers were tested and each suffered the same deformation. However, when testing fifty polycarbonate containers under the same conditions, no deformation was detected. A photograph of a polycarbonate container is also attached as Exhibit 2. The polycarbonate

container has been subjected to the same conditions as the PET container and can be seen to have sustained no ballooning deformation.

To summarize, as well as there being no build up of medicament on the container wall, of the polycarbonate of the instant invention, the use of polycarbonate also overcomes a problem of creep deformation at higher ambient temperatures due to the pressure exerted by propellants in the container.

The Jordan references does not recognize the problem of medicament build up nor the problem of creep deformation where plastics materials, even if transparent plastics are used, for metered dosed inhalers (MDI) containers.

In view of the foregoing, applicants respectfully submit that the Examiner's citation of *In re Leshin*, 125 USPQ 416 is inapposite to the present invention because the entire disclosure of Jordan is that any transparent plastic material can be utilized for a container for an MDI. However, applicants have shown that the particular material imparts unobvious properties, such as when the selection of polycarbonate is utilized as an MDI container. The polycarbonate does not have build up of medicament on its interior nor is it susceptible to higher ambient temperature deformation, as are other transparent plastics such as PET. In view of the foregoing withdrawal of the rejection is respectfully requested.

Reconsideration of the rejection claims 6 under 35 U.S.C. 103 (a) as being unpatentable over Jordan in view of Morris, Jr (U.S. Patent 4,105,142) is respectfully requested. The deficiencies of the Jordan reference have been noted above which deficiencies are herein incorporated by reference as though fully set forth herein. The Morris, Jr. reference does not correct the forgoing deficiency noted in Jordan and expressly does not teach or suggest the use of a polycarbonate, nor in fact any particular material, as the container for medicament. Thus, the proposed combination of Jordan in view of Morris, Jr. does not establish a prima facie case of obviousness for the invention as claimed in claim 6 which, being dependent on claim 1, incorporates by statute (35 U.S.C. 112 fourth paragraph)

all the limitations of the claim 1 upon which it depends. Accordingly, withdrawal of the rejection is therefore respectfully requested.

Reconsideration of the rejection of claims 7-9 and 18 under 35 U.S.C. 103 (a) as being unpatentable over Jordan in view of Dickinson et al (U.S. Patent 6,737,044) is respectfully requested.

With regard to the rejection of these claims, not only do these claims incorporate all the limitations of claim 1 upon which they directly (or indirectly) depend but they also include specific pharmaceutical formulations, which the Examiner also acknowledges that Jordan "fails to disclose the formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant". While Dickinson et al. discloses another dispenser for these pharmaceuticals, applicants are not claiming that the pharmaceuticals, *per se*, are novel but rather that the combination of a polycarbonate container in an MDI would these particular pharmaceuticals is "novel and unobvious". Dickinson et al does not cure the forgoing deficiencies of Jordan, nor in fact does it teach that if any transparent plastics is used with these pharmaceuticals that the problems of build up on the container would not still be found. Thus, the proposed combination still does not establish a prima facie case of obviousness for the claimed invention.

Lastly, reconsideration of the rejection of claim 13 under 35 U.S.C. 103 (a) as being unpatentable over Jordan in view of Hutchinson et al (U.S. Patent 6,352,426) is respectfully requested. While it is alleged that Hutchinson et al reference "discloses that injection molding and injection blow molding are commonly known methods of making containers in the art" Hutchinson et al does not injection or blow mold polycarbonates, but rather Polyethelyene Terephthalate (PET) previously discussed which, as is known in the art, is a polyester not a polycarbonate. Thus, for all the foregoing reasons applicants respectfully submit that the Examiner has failed as a fact finder to locate prior art documents that teach the various aspects of the claimed invention. While the invention may be considered one of a

combination of various known elements, the Examiner's initial burden, in any 35 U.S.C. 103 (a) rejection based on obviousness, is to find the various aspects of the claimed invention in the prior art. Having failed to cite any references to show those aspects, it can only be presumed that the prior art does not teach those aspects. In such a case, the Examiner should have allowed the claimed invention as being both novel and unobvious. Such allowance is respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8693.014.US0000.

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Respectfully submitted,



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